

PATENT
28053/37955

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:)	I hereby certify that this paper is being
)	deposited with the U.S. Postal Service
Ian L. BROWN et al.)	as First Class Mail in an envelope,
)	postage prepaid, addressed to the
Serial No.: 10/009,023)	Commissioner for Patents, P.O. Box
)	1450, Alexandria, VA 22313-1450
Filed: April 12, 2002)	
)	June 7, 2004
For: Starch Sub-Types)	
And Lipid Metabolism)	
)	
Group Art Unit: 1623)	
)	
Examiner: L. Maier)	Jeffrey S. Sharp

DECLARATION OF Ian L. Brown
PURSUANT TO 37 CFR § 1.132

I, Ian L. Brown, a resident of the United States, residing at 24 Hancock Court, Basking Ridge, New Jersey 07920, hereby declare that:

1. I am a co-inventor of the invention disclosed and claimed in the above-identified patent application, U.S. Patent Application Serial No. 10/009,023 ("the patent application"), originally filed on April 6, 2001 as a §371 of PCT/AU01/00392. As such, I am thoroughly familiar with the patent application as originally filed and amended.
2. My qualifications and technical experience are set out in my *curriculum vitae*, a copy of which is attached as Appendix A.
3. I have read and understand the official action from the U.S. Patent and Trademark Office (the "Patent Office") dated January 7, 2004 (the "Office Action"), which was issued in connection with U.S. Patent Application Serial No. 10/009,023. I also have reviewed and understand the patents and publications cited by the Examiner in the Office

Action. Finally, I have been informed of the point raised by the Examiner in the Personal Interview conducted with Applicants' attorney on May 12, 2004 in which she raised the issue of what portion of starch was intended by the claim recitation of "resistant starch." I make this Declaration to provide information known to me that may be relevant to various claim rejections in the Office Action.

4. The Examiner raised an issue regarding the definiteness of the claim recitation of "resistant starch." In particular, the Examiner raised the issue of whether the recitation of "resistant starch" referred to the quantity of the resistant starch content of a resistant starch containing starch (e.g., high amylose starch) or to the resistant starch containing starch as a whole. Those of skill in the art of starch chemistry would recognize that a reference to "resistant starch" in conjunction with quantitative terms such as percentages (e.g., 10% resistant starch) or weights (e.g., 2 grams resistant starch) in the claims would refer to that portion of the starch which is resistant and not to the non-resistant starch portion of the starch.

5. Resistant starch is starch which when consumed resists enzymatic digestion and acts like dietary fiber. Brown et al., Food Australia 47: 272-275 (1995) referred to at page 5, lines 20 and 21 in Applicants' specification notes that European Food-Linked Agro-Industrial Research - Concerted Action on Resistant Starch 1991 (EURESTA) defined resistant starch as "the sum of starch and products of starch not absorbed in the small intestine of healthy individuals." (Brown et al., p. 272 Resistant starch exists in several types RS1 (physically inaccessible starch), RS2 (resistant starch granules such as present in high amylose starch), RS3 (retrograded starch, such as heat and moisture treated), and RS4 (chemically modified starch, such as starch esters and ethers and crosslinked starches)).

6. As noted in the specification and in prior art literature, resistant starch is present in various proportions in different natural and processed starches. Such starches are referred to as having a resistant starch content by which is meant that proportion of the product or starch which is resistant to enzymatic digestion. Thus, the specification at page 3, lines 18-22 refers to "constituents with a low resistant starch content" and with "a high resistant starch content." Further, the specification teaches at page 6, lines 12-13 that "[s]tarches can also be treated to enhance the resistant starch content by a number of physical

or chemical means." Applicants also refer to the disclosure of McNaught et al. WO 94/14342 (pg. 4, Table 1) in which the resistant starch levels of various maize starches from waxy maize to high amylose starch are analyzed. (As discussed later, this reference teaches that waxy maize starch has a low resistant starch content while high amylose starches tend to have higher resistant starch contents increasing with higher amylose levels.) Further, Example 4 of Applicants' specification refers to the resistant starch content of both "traditional" starches and Hi-maize™ high amylose starches (See page 25, line 21). The claims of the present application also distinguish between resistant starch and starch which comprises a resistant starch component. See claim 13 which specifies that "resistant starch is present in a proportion of at least 5% by weight of the total starch content."

7. While starches such as high amylose starch might occasionally be informally referred to as "resistant starch" the use of the term "resistant starch" in conjunction with a percentage or weight would invariably be understood by those of skill in the art to refer to the resistant starch portion of that starch. Hence the reference to resistant starch content in the specification at page 3 as well as the discussion in the application Examples makes clear that quantitative references to "resistant starch" are to the resistant starch portions of starches and food products comprising resistant starch. Thus, while the application examples and disclosures such as McNaught WO 94/14342 make clear that even though traditional starches and starch containing food products may have a resistant starch content, they are not resistant starch. Similarly, products comprising high amylose maize starch have a resistant starch content but are not "resistant starch."

8. Various claims stand rejected as being anticipated by the disclosure of Laughlin et al. U.S. Patent No. 5,470,839 on the basis that Laughlin discloses replacement of "at least 5% of an individual's daily carbohydrate intake with resistant starch and at least 10% of the individual's saturated fat intake with unsaturated fat." I further submit this Declaration, to establish that Laughlin fails to disclose that element of the present invention that calls for replacement of "at least 10% of an individual's daily carbohydrate intake with resistant starch."

9. Even in high amylose maize starch the amount of resistant starch is a fraction

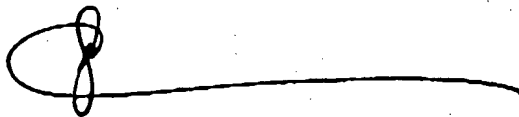
of the total starch content. While Laughlin teaches the incorporation of high amylose starch as one carbohydrate component of its dietary formulation, it should be noted that only a small fraction of high amylose starch is resistant starch. In particular, the resistant starch content of high amylose starch varies in the range of from 7.5% (High Amylose 50, i.e. 50% amylose) to 22% (High Amylose 80, i.e., 80% Amylose). (See Table 1, page 4, of McNaught et al. WO 94/14342 which analyzes the resistant starch content in various high amylose starches; see also Brown, McNaught and Moloney (1995) Food Australia 47: 272-275 (see Page 5, Lines 19-21) which discloses that, "[a] number of factors may cause starch to be resistant to digestion, including the size of the starch-containing fragments e.g., in kibbled grains, the structure and conformation of intact starch granules, the formation of retrograded crystallites as a result of processing, and chemical modification (Table 1)." (See Page 272, Column 2, Lines 18-23).) When this is combined with the recognition that Laughlin never discloses high amylose as comprising greater than 23% of carbohydrate content it is clear the resistant starch content of the Laughlin formulations would never exceed 5% (i.e., $23\% \times 22\% = 5\%$).

10. Laughlin et al. does not disclose or suggest an amount of resistant starch which is an essential feature of the present invention. Importantly, Laughlin et al. fails to recognize the importance of the resistant starch content. Laughlin et al. does provide a diet comprising a high amylose starch, but does not disclose the amount of resistant starch present in the composition. Nor does Laughlin et al. disclose the grain from which the starch is produced or the size of the starch granule, so that even with the benefit of hindsight it is not possible to estimate the amount of resistant starch present.

11. For these reasons, the Laughlin et al. reference fails to disclose or teach that aspect of the invention that calls for replacement of "at least 10% of an individual's daily carbohydrate intake with resistant starch."

12. I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or document or

any patent which may issue thereon.

A handwritten signature in black ink, consisting of a large loop followed by a horizontal line.

Ian L. Brown, Ph.D.

Date: 7 June 2004



IAN LEWIS BROWN

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- Present Position:** Senior Director – Nutrition, National Starch and Chemical Company.
10 Finderne Avenue,
Bridgewater, 08807 New Jersey USA.
Tel: +1 908 685 5376 ; email – ian.brown@nstarch.com
- Education:** High School Diploma (1976) Forest Park, Ohio, USA.
Higher School Certificate (1976) NSW, Australia.

Bachelor of Science. (1981) The University of New England, Australia.

Diploma of Education. (1981) The University of New England.

Diploma of Business Studies. (1989) The University of New England.

Master of Science (Biochemistry). (1995) The University of New England.
Thesis entitled "The structure of Australian maize starch"

Doctor of Philosophy (Applied Bioscience, Graduate School of Agriculture).
(1999) The University of Hokkaido, Japan.
Thesis entitled "The development and application of high amylose maize starches
for food, nutritional benefit and public health".
- Appointments:** 2004 - Visiting Professor, School of Medicine
University of Colorado Health Sciences Center
[Colorado University, USA]

2000 - Professorial Fellow, University of Wollongong
[ARC Smart Foods Key Centre & Faculty of Health & Behavioural Sciences,
University of Wollongong, Australia]

2000 - Member of Advisory Board for Australian Research Council (ARC)
Key Centre for Smart Foods.
[University of Wollongong, Australia]

2003 - Senior Director - Nutrition, National Starch and Chemical Company.
- Professional Associations:** 1985 - 2001 Foundation Member of the Australian Biotechnology Assoc.
1986 - Member of the Royal Australian Chemical Institute.
1986 - Professional Member of the Australian Institute of Food Science & Technology.
1986 - Professional Member of the Institute of Food Technologists
USA.
1990 - Associate Fellow of the Australian Institute of Management.
1994 - Member of the Nutrition Society of Australia.
2000 - Professional Member of the American Association of Cereal Chemists.
- Awards:** 1975-76 American Field Service Scholarship to study in the USA for 12 months.

1977-80 NSW Department of Education Teaching Scholarship.

1994 RACI (Royal Australian Chemical Institute) **Cereal Chemistry Division Poster Paper Award – Best Visual Presentation.**

1995 RACI (Royal Australian Chemical Institute) **Cereal Chemistry Division Poster Paper Award – Best Poster Contributed by a Commercial Industry Laboratory.**

1995 AIFST (Australian Institute of Food Science & Technology) **Food Industry Innovation Award.**

1999 AIFST (Australian Institute of Food Science & Technology) **The Jack Kefford Award for the Best Paper Published in "Food Australia" in 1998.**

Government:

1998 – 1999. Member of the external technical advisory committee that assisted in the preparation of the Australian & New Zealand Food Authority Full Assessment Report. Proposal P177. Derivation of Energy Factors. February 1999 [Development of Joint Australian New Zealand Food Standards as part of the process of the Review of the Food Standards Code].

2000 - 2001. Member of the Expert Working Group on Dietary Fibre for the Australian & New Zealand Food Authority.

Patents:

Co-inventor of 10 USA patents (more than 32 patents granted internationally in other countries) concerning maize varieties, starch production, resistant starch and dietary fibre utilisation, nutrition, prebiotic functionality of starch and other food ingredients, treatment of human and animal diseases, and the physiological action of starch and other dietary components.

Publications:

Published 27 papers and one book chapter in a variety of international scientific journals on topics concerning cereal science, starch chemistry, food engineering, nutrition and microbiology.

Some 38 other publications have been authored in association with conferences and symposia in Australia and overseas.

Provided educational segments for courses sponsored by the Bread Research Institute, Royal Australian Chemical Institute and University of Wollongong.

Invited & Plenary Presentations:

Australia:

Invited to present oral papers at 19 conferences and symposia in Australia.

International:

Invited to provide oral papers or chair meetings at 16 international conferences and symposia in Japan, Singapore, Malaysia, New Zealand, USA, Canada, Korea, Ireland and the Philippines.

Committees:

Honorary Treasurer for 3rd International Food Hydrocolloids Conference. Sydney. (1996).

Member of the Management Committee of the Cooperative Research Centre for Food Industry Innovation (1996 - 00).

Grants:

Successful in obtaining research grants through AIR&DIB and Food into Asia schemes.

Ian Lewis Brown

7 June 2004